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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,327	03/30/2005	Harri Savilahti	0933-0230PUS1	6680
2292	7590	01/25/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			KATCHEVES, KONSTANTINA T	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1636	
DATE MAILED: 01/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/511,327	SAVILAHTI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5 and 8-13 is/are rejected.
- 7) Claim(s) 6 and 7 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 October 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/15/04
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-13 are pending in the instant application.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-8 and SEQ ID NO:1, in the reply filed on 03 November 2005 is acknowledged. Upon consideration of Applicant's arguments the restriction requirement set forth in the prior Office action is withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 8-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

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Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."

See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The invention of the instant claims is drawn to a "transposon nucleic acid comprising genetically translation stop signal in three reading frames at least partly within a transposon end sequence." This nucleic acid is recognized by a tranposase. This is a broad genus claim. The specification only discloses three representative species. The specification does not describe the members of the genus in such a way such that one of skill in the art at could reasonably conclude that Applicant possession of the entire genus. The genus claimed includes include any modified transposon. The breadth of the invention is not supported or described by the limited species disclosed in the specification. The specification is limited to disclosure of four species (SEQ ID NO:1, 2, 5, and 7) without a description of any structural components which are common to the broad species as a whole. Indeed, these four species are actually derived from Tn7 and Mu.

The claims also recite embodiments wherein the transposon end sequence is Mu or Tn7, the transposon end sequence is an end binding sequence or the end sequence is a Mu R-end binding sequence. Again these are genuses, which are not described in the specification in such a way as to indicate that Applicant had possession of the genus claimed. As discussed above, the disclosure is limited to a single Mu transposon

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nucleic acid (SEQ ID NO:2) and a single Tn7 transposon nucleic acid (SEQ IDNO:7).

See Specification page 8, line 4-5. SEQ ID NO:1 and SEQ ID NO:5 merely describe Mu R-end sequences. See Specification page 9, lines 5-6. These two species do not describe the entire genus claimed because Applicant has not disclose shared structural characteristics as they related to function, i.e. transposase recognition to describe the genus of Mu or Tn7 end sequences. Even the genus of Mu R-end sequences in not adequately described because the modification within the Mu R-end sequence could be anywhere within the end and in any of the three reading frames such that recognition by a transposase is maintained. Applicant has not disclosed where structurally such modifications just within the Mu R-end sequence can be tolerated.

Therefore, the specification neither describes the complete structure of a representative number of species nor does the specification describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance as to the structure-function relationship of these sequences, the specification does not describe the claimed genus in such full, clear, concise and exact terms so as to indicate that Applicant had possession of them at the time of filing of the present application.

#### **Prior Art Not Relied Upon**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. York et al. (Nucleic Acids Research, 1998 Vol. 26, No.8), made of record by Applicant on the IDS 15 October 2004, is noted by the examiner as

indicative of the closest prior art. York et al. explicitly teaches that the stop codons found in all three reading frames are immediately adjacent to the end sequences. Claim 1, on the other hand, explicitly claims that the stop codons are "at least partly within" the end sequence. Therefore, York et al. fails to read on the claim. Moreover, one would not be motivated to modify the end sequence with an overlapping end sequence because the modification of the end sequence could affect the function of the ability of the transposase to recognize the end sequence.

### ***Allowable Subject Matter***

Claims 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Konstantina Katcheves  
Examiner  
Art Unit 1636